

REMARKS

The above-referenced application has been reviewed in light of the Office Action mailed March 3, 2006. It is respectfully submitted that the claims pending in the application do not introduce new subject matter, are fully supported by the specification, and are patentable over the cited prior art. Prompt and favorable consideration of these claims is earnestly sought.

In the Office Action, claims 1 and 4-12 were rejected under 35 U.S.C. § 102 (b) as anticipated by or, in the alternative, as obvious under 35 U.S.C. § 103 (a) over U.S. Patent No. 3,875,595 to Froning (the '595 patent). The Office Action characterized the '595 patent as disclosing a cannula and a retractor including a shaft and an inflatable bladder. The Office Action asserted that the inflatable bladder is inherently capable of retracting opposed surfaces of a bone joint since the inflation of the bladder would inherently apply an outward pressure against the opposed surfaces to retract them. The Office Action stated that, alternatively, it would have been obvious that inflatable bladder is capable of retracting opposed surfaces of a bone joint for the same reasons. Applicant respectfully disagrees for the reasons below.

The '595 patent relates to a system for replacing a nucleus of an intervertebral disc with a prosthesis. In particular, the '595 patent discloses (Column 1, lines 7-9) that a "principal purpose of the present invention is to provide a prosthetic replacement for a damaged intervertebral disc." According to the '595 patent, (Column 3, lines 17-21 and 33-38, and Figure 5 reproduced below) that prosthesis 46 is formed from a material that has such that the prosthesis holds water or fluid under pressure and substantially duplicates the normal disc. As shown and disclosed in the '595

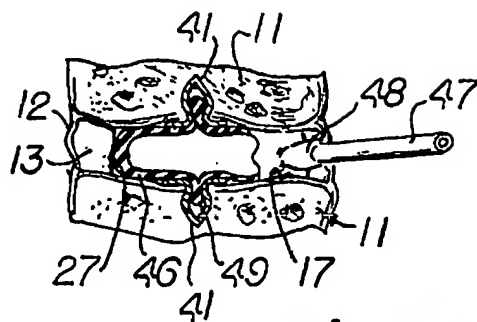


Fig. 5

patent, the prosthesis 46 is a closed envelope attached to the distal end of the shaft 47 using a check valve 48. According to the '595 patent (see Column 3, lines 33-43), fluid is introduced in to the prosthesis 46 to expand it to the condition shown in Figure 5, thereby "filling the void 17." The void 27 is previously defined by the removal of the disc nucleus via chemonucleolysis (col. 2, lines 10-17) or via forceps (Fig. 2, col. 1, lines 54-57). By filling this void 27, however, Froning is entirely silent about separating opposed surfaces when its prosthesis 46 is inflated. In fact, Froning only discloses the use of an instrument (not shown) to spread apart adjacent vertebrae (col. 2, lines 38-47). Pins 33 and 33a are inserted into adjacent vertebra to hold them spread apart.

The Applicant respectfully disagrees with the Examiner's assertion that the inflatable bladder of Froning inherently separates opposed surfaces of a bone joint. As stated in the M.P.E.P. §2112, IV, to establish inherency, the missing descriptive matter must necessarily be present in the reference: here, the Froning inflatable bladder need not separate opposed surfaces because a separate instrument previously separates the opposed surfaces. Similarly, Froning fails to suggest an inflatable bladder that separates opposed surfaces, but instead teaches away from such an inflatable bladder by using a separate instrument for distraction when needed. The

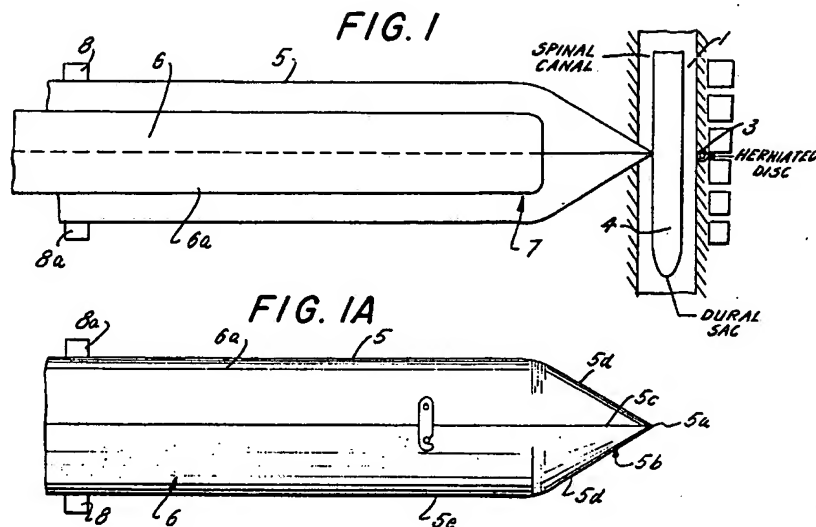
Examiner's characterization of the Froning inflatable bladder goes too far; just because an inflatable bladder is inflated with water does not mean that the pressure is sufficient to move opposed surfaces such as vertebral end plates or that the inflatable bladder can handle such a pressure without rupturing.

Therefore, the '595 patent fails to disclose or suggest a system as recited in amended claim 1. Therefore, it is respectfully submitted that claim 1 is neither anticipated nor suggested by the '595 patent and the rejection of the Office Action should be withdrawn. Since claims 4-12 depend directly or indirectly from claim 1, it is respectfully submitted that these claims are not anticipated or suggested by the '595 patent and the rejection of the Office Action has been overcome.

In the Office Action, claims 1 and 4-12 were rejected under 35 U.S.C. § 102 (b) as anticipated by or, in the alternative, as obvious under 35 U.S.C. § 103 (a) over U.S. Patent No. 4,341,745 to Sheldon (the '745 patent). The Office Action characterized the '745 patent as disclosing a shaft, an inflatable bladder which has an eccentric shape upon inflation, and a cannula. The Office Action asserted that the inflatable bladder has the shape of a wedge since it tapers in the proximal direction and is inherently capable of separating adjacent layers of tissue since it is made from Mylar and inflated with a substantially non-compressible fluid.

Contrary to the position taken in the Office Action, the '745 patent does not disclose a cannula; the '745 patent, as shown below in Figures 1 and 1A, discloses a needle 5 with an open proximal end and a **closed distal end**. Specifically, the '745 patent discloses (see Column 3, lines 6 and 7) that the "shaft 5e of the needle terminates a few millimeters before the distal point of the needle 5a." Thus, the '745 patent discloses a needle having a closed distal end that

terminates in a point. This construction is necessary for the proper functioning of the disclosed device.



According to the '745 patent disclosure (see Column 9, lines 32-34), "the needle 5 has to penetrate into the spinal sac by puncturing the dura and entering the subarachnoid space." In support of puncturing the dura, the disclosed device requires a distal point.

Therefore, the '745 patent fails to disclose or suggest a system including, *inter alia*, a cannula as recited in claim 1. Therefore, it is respectfully submitted that claim 1 is neither anticipated nor suggested by the '745 patent and the rejection of the Office Action has been overcome. Since claims 4-12 depend directly or indirectly from claim 1, it is respectfully submitted that these claims are not anticipated or suggested by the '745 patent and the rejection of the Office Action has been overcome.

Appl. No. 10/752,933

Amdt. dated June 5, 2006

Reply to Office Action mailed March 3, 2006

In view of the foregoing remarks, it is respectfully submitted that all claims pending in the application, namely claims 1 and 4-12, are in condition for allowance. Should the Examiner desire a telephonic interview to resolve any outstanding matters, the Examiner is sincerely invited to contact the undersigned at (631) 501-5713.

Respectfully submitted,

A handwritten signature in cursive script, reading "David M. Carter", is written over a horizontal line.

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